

REMARKS

In the office action, claim 9 has been rejected under 35 U.S.C. §102, and claims 9, 10 and 15 have been rejected under the judicially created doctrine of nonstatutory obviousness-type double patenting; and under 35 U.S.C. §103.

In response, Applicant submits the following amendments, terminal disclaimer and remarks. Claim 10 has been cancelled and claims 9 and 15 have been amended. Claims 9 and 15 are presently pending in the application.

The Invention

The present invention is a composition *consisting essentially of* gamma vinyl GABA and vitamin B6. The basic and novel characteristics of the claims are 'gamma vinyl GABA' and 'vitamin B6'.

From reading the specification, it is clear that gamma vinyl GABA (GVG) is involved in several chemical reactions in the brain. For example, on page 5, lines 7-9, the inventors discuss some of these reactions. The effect that GVG has on the many chemical reactions of the brain is highly influenced by the presence of other compounds. For this reason, Applicants used the transitional phrase "consisting essentially of" in the claims. The addition of compounds, other than GVG and vitamin B6, to the claimed composition, would constitute a material change to the basic and novel characteristics of the invention.

Double Patenting

In the office action, claims 9, 10 and 15 have been rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-8 of U.S. Patent No. 6,713,497 B1. In response, Applicants submit herein a terminal disclaimer in compliance with 37 C.F.R. 1.321.

Accordingly, Applicant respectfully requests that the rejection based on nonstatutory obviousness-type double patenting be withdrawn.

35 U.S.C. §102

Claim 9 has been rejected under §102(b) as being anticipated by Blum et al. (U.S. Patent No. 5,189,064). According to the Examiner, Blum et al. disclose a composition containing amino acids and analogs of GABA and GABA precursors. The Examiner refers to claim 10 of Blum et al.

Claim 10 is for a composition consisting essentially of:

(a) an opiate destruction-inhibiting amount of at least one substance...selected from...

- (i) amino acids
- (ii) peptides
- (ii) analogs or derivatives of (i) or (ii); and

(b) a neurotransmitter synthesis-promoting amount of at least one neurotransmitter precursor selected from...L-tyr, L-Phe and L-dopa..., L-trp and 5-hydroxytryptophan, and...L-glutamine, L-glutamic acid and L-glutamate...

There is no disclosure in Blum et al. of a composition containing GVG and vitamin B6.

The Examiner points to an example from Blum et al. of an amino acid formulation containing L-glutamine and vitamin B6 (Example 1). The formulation disclosed in Example 1 is an amino acid formulation containing 15 ingredients. None of the ingredients is gamma vinyl GABA. Vitamin B6 (pyridoxal phosphate) is one of the ingredients listed. However, Blum et al. disclose the daily dosage of vitamin B6 to be 20 mg/day.

Applicant has amended claim 9 to be directed to a composition consisting essentially of gamma vinyl GABA (GVG) and vitamin B6, wherein the amount of vitamin B6 is about 50 to 100 mg/day.

There is no disclosure in Blum et al. of a composition containing GVG and vitamin B6. Furthermore, there is no disclosure in Blum et al. of a composition containing GVG and vitamin B6, wherein the amount of vitamin B6 is about 50 to 100 mg/day.

Blum et al. do not anticipate the claimed invention. Accordingly, Applicant respectfully requests that the rejection under §102 (b) based on Blum et al. be reconsidered and withdrawn.

Claim 9 has been rejected under §102(a) as being anticipated by Evans et al. (U.S. Patent Application Pub. No. 2002/0048612 A1). According to the Examiner, Evans et al. disclose a composition that contains a GABA substrate and various vitamins and cofactors. The Examiner points to an example from Evans et al., of a composition containing vitamin B6, magnesium butyrate and calcium butyrate.

There is no disclosure in Evans et al. of a composition containing GVG and vitamin B6.

The Examiner points to a specific example from Blum et al. of a composition containing vitamin B6, magnesium butyrate and calcium butyrate (Table 1). The composition does not contain gamma vinyl GABA. The composition in Evans et al. that the Examiner refers to discloses the dosage of vitamin B6 to be 30 mg/day.

Applicant has amended claim 9 to be directed to a composition consisting essentially of gamma vinyl GABA (GVG) and vitamin B6, wherein the amount of vitamin B6 is about 50 to 100 mg/day.

There is no disclosure in Evans et al. of a composition containing GVG and vitamin B6. Furthermore, there is no disclosure in Evans et al. of a composition containing GVG and vitamin B6, wherein the amount of vitamin B6 is about 50 to 100 mg/day.

Evans et al. do not anticipate the claimed invention. Accordingly, Applicant respectfully requests that the rejection under §102 (b) based on Evans et al. be reconsidered and withdrawn.

35 U.S.C. §103

Claims 9, 10 and 15 have been rejected under §103(a) as being unpatentable over Blum et al. According to the Examiner, Blum et al. discloses a composition containing amino acids and analogs of GABA and GABA precursors. The Examiner contends that Blum et al. disclose that administration of GVG in animals inhibits GABA-T and increases GABA concentrations.

The Examiner recognizes that Blum et al. do not specifically teach a composition containing GVG and vitamin B6. However, according to the Examiner, the skilled artisan would have been motivated to make a composition containing GVG and vitamin B6, having been taught by Blum that GVG and vitamin B6 increase GABA concentrations. The Examiner also contends that the skilled artisan would have been further motivated by the fact that vitamin B6 works to increase GABA concentrations at two points along the synthetic pathway, i.e. as factors for GAD and GABA-T.

Applicant fails to appreciate why a skilled artisan would be motivated to make the claimed composition based on the Examiner's above reasoning, i.e. "the fact that vitamin B6 works to increase GABA concentrations at two points along the synthetic pathway" and "GVG and vitamin B6 increase GABA concentrations."

Importantly, Blum et al. do not disclose or suggest a composition consisting essentially of GVG and vitamin B6. Blum et al. disclose compositions containing 15 or more ingredients - not including GVG. The addition of ingredients other than GVG and vitamin B6 would constitute a material change in the basic and novel characteristics of the claimed invention. See above section entitled "The Invention."

Even more importantly, as mentioned above, Blum et al. disclose the use of vitamin B6 at a daily dosage of 20 mg/day.

In order to establish a prima facie case of obviousness, there must be some suggestion or motivation to modify the reference, there must be a reasonable expectation of success and the prior art reference must teach all of the claim limitations. See MPEP 2143.

Applicant has emphasized the importance of the composition consisting essentially of GVG and vitamin B6, and wherein the vitamin B6 is in an amount of about 50 to 100 mg/day. Blum et al. simply do not disclose or suggest the claimed composition.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under §103 based on Blum et al.

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In light of the foregoing remarks, Applicant respectfully submits that the application is now in condition for allowance. If the Examiner believes a telephone discussion with the Applicant's representative would be of assistance, she is invited to contact the undersigned at her convenience.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Ch Brakel', written in a cursive style.

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